



TRUEbalance™

QUALITY ASSURANCE AND QUALITY CONTROL REFERENCE GUIDE FOR MULTI-PATIENT USE FACILITIES

Information in This Manual is Specific for Healthcare Providers

www.homediagnostics.com

1-800-803-6025 or 1-954-677-4599.

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TRUEbalance™

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**TRUEbalance[®] QUALITY ASSURANCE AND
QUALITY CONTROL REFERENCE GUIDE
FOR MULTI-PATIENT USE FACILITIES**

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This Manual is intended for use by the Healthcare Professional for point-of-care testing. Please read the **TRUEbalance™** Owner's Booklet and all product Instructions for Use carefully before referencing or using this Manual.

TRUEbalance™

TRUEbalance™ Quality Assurance / Quality Control Manual

Introduction

Home Diagnostics, Inc (HDI) is proud to present the TRUEbalance Blood Glucose Monitoring System, a no coding system. A no coding system means that the Meter does not have to be coded to each test strip. The Quality Assurance/Quality Control Manual is designed for use specifically by the Healthcare Professional for point-of-care testing in a multi-patient, multi-user setting. Healthcare Professionals in your facility now have a very simple and accurate way to safely test blood glucose levels in your patients.

Home Diagnostics, Inc. recognizes the importance of practicing safe and reliable testing using the TRUEbalance Blood Glucose Monitoring System. Therefore, this Manual has been designed to provide the following:

- A basic understanding of the TRUEbalance System,
- A detailed testing guide,
- Quality Control Program recommendations for the TRUEbalance System in your facility,
- A complete guide to troubleshooting issues and concerns that may arise with using the TRUEbalance System in patient care,
- A comprehensive HDI certified training program for Healthcare Professionals that will be using the TRUEbalance System.

CAUTION!

Please read this entire Manual and all product Instructions for Use before testing.

CAUTION!

DO NOT change patient medication, diet, or exercise routine without consulting the patient's Doctor or Diabetes Healthcare Professional.

Use of TRUEbalance in a manner not specified in this Manual is not recommended and may affect the ability to determine true blood glucose levels.

Our goal is to provide quality healthcare products and dedicated customer service. For questions about the TRUEbalance products, visit our website at **www.homediagnostics.com**.

TRUEbalance™ Quality Assurance / Quality Control Manual

Table of Contents

| | |
|-----------------------------------------------------------------|--------------|
| Introduction | 2 |
| Table of Contents | 3 |
| Section 1: Using TRUEbalance in a Clinical Setting | 4-16 |
| Section 2: Description of System | 17-21 |
| Section 3: Quality Control Testing | 22-26 |
| Section 4: Blood Glucose Testing | 27-31 |
| Section 5: Set Up of Time and Date | 32-33 |
| Section 6: Memory | 34-35 |
| Section 7: Care and Storage of System | 36-38 |
| Section 8: Troubleshooting | 39-42 |
| Section 9: Training Certification Program | 43-50 |
| Section 10: Forms | 51-53 |
| Section 11: TRUEbalance Lifetime Warranty | 54-55 |
| Section 12: References | 56-57 |



Section 1:

Using TRUEbalance™ in a Clinical Setting



TRUEbalance™ Quality Assurance / Quality Control Manual

Limitations

- Please read all product Instructions for Use carefully before referencing or using this Manual.
- Use only TRUEbalance Blood Glucose Test Strips and TRUEcontrol Glucose Control Solution when testing with the TRUEbalance Meter.
- Perform Glucose Control Tests ***before*** performing a blood glucose test (*see Section 3: Quality Control Testing*), when using the System for the first time. Three levels of TRUEcontrol Glucose Control Solution are available for Quality Control Testing. Contact your distributor to order different levels of Glucose Control Solution. We recommend testing at least 2 levels of Control. For testing frequency and the number of Control levels to test, refer to your facility quality control procedure/policy.
- TRUEbalance is an *in vitro* quantitative system that is used for self testing and point-of-care testing of human whole blood only.
- The most accurate results are obtained using fresh, capillary whole blood from the fingertip. Serum, clotted blood, venous blood or plasma cannot be used with the TRUEbalance System.
- Capillary blood from the forearm may be used. Check with the Doctor or Healthcare Professional to see if forearm testing may be used for glucose testing on the patient. Results from the forearm are not always the same as results from the fingertip. Use fingertip instead of forearm:
 - Within 2 hours of eating, exercise, or taking insulin,
 - If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate,
 - If the patient is ill or under stress,
 - If the glucose result may be low or high,
 - If symptoms of low or high glucose levels are not evident.¹
- For evaluation where TRUEbalance blood glucose values are compared to blood glucose values given by a laboratory, it is recommended that capillary blood obtained from the same site be used for both the laboratory instrument as well as the TRUEbalance System. Laboratory tests should be performed within 30 minutes of a blood glucose meter test to minimize the changes in glucose values due to glycolysis. Results from the TRUEbalance System are considered accurate if within $\pm 20\%$ of laboratory results. If patient has recently eaten, finger results from the TRUEbalance System can be up to 70 mg/dL higher than venous laboratory results.²

TRUEbalance™ Quality Assurance / Quality Control Manual

- The TRUEbalance System cannot be used in the diagnosis of diabetes or to test blood glucose in neonates.
- Inaccurate results may occur in severely hypotensive patients or patients in shock. Inaccurate results may occur for patients experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with a blood glucose meter.³
- Testing at altitudes up to and including 10,150 feet will not affect accurate results.⁴
- Hematocrit levels between 30% and 55% will not affect accurate results.⁴

TRUEbalance™ Quality Assurance / Quality Control Manual

Expected Results

Each patient should have specific blood glucose target ranges that are determined by the Doctor or Diabetes Healthcare Professional. Having most blood glucose results within the patient's target range shows how well a treatment plan is working to control glucose levels. Keeping results within the patient's target range helps slow or stop complications from diabetes.

Expected Results for people without diabetes⁵:

| | <u>Plasma Blood Glucose Result</u> |
|-----------------------|------------------------------------|
| Before eating | <126 mg/dL |
| Two hours after meals | <200 mg/dL |

- Low blood glucose (hypoglycemia) symptoms may include trembling, sweating, intense hunger, nervousness, weakness or trouble speaking.
- High blood glucose (hyperglycemia) symptoms may include intense thirst, a need to urinate often, a dry mouth, vomiting, or headache.

If the patient is showing any of these symptoms, check their blood glucose. If any result seems higher or lower than expected, repeat the test with a new Test Strip. Contact the Doctor or Diabetes Healthcare Professional with any unusual results.

TRUEbalance™ Quality Assurance / Quality Control Manual

Regulatory Requirements - CLIA

Self-testing and point-of-care testing of blood glucose has been classified by the Clinical Laboratory Improvement Amendments (CLIA) as a waived test. CLIA requires all entities that perform even one test, including waived tests, (on materials derived for the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings) to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program.

Waived laboratories must meet the following requirements:

- Complete the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Application for Certification, Form CMS-116. The form and instructions on completing and mailing the form are found on http://www.cms.hhs.gov/CLIA/06_How_to_Apply_for_a_CLIA_Certificate_Including_Foreign_Laboratories.asp#TopOfPage.
- Pay applicable certificate fees biennially.
- Follow manufacturer's test instructions, including instructions for Quality Control, maintenance, and storage instructions.

Upon approval of Form CMS-116, a Certificate of Waiver is forwarded to the laboratory.

For more information on the CLIA program, see <http://www.cms.hhs.gov/CLIA/>.

For a comprehensive look at waived testing, see <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>.

TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose Monitoring System

Proficiency Testing Information

The objective of proficiency testing is to qualitatively determine the skill of the user of a specific product and the accuracy of the results obtained using the product. Participating laboratories receive specimens from a distributor, test the specimens and report the results back to the distributor. The results of all participants are summarized in a report that is sent to the participating laboratories. The report contains an evaluation of the individual laboratory performance as well as a comparison to a summary of results from other participating labs.

It is important to be aware that proficiency samples are not fresh blood and may behave differently on different glucose test systems. The accuracy of the result from a proficiency sample is not an indicator of the accuracy of your system when tested with fresh whole blood obtained from a patient. The proficiency testing only serves to show how your results compare to other TRUEbalance system users. If your proficiency sample results are not within acceptable limits of other TRUEbalance users' results, then you should investigate possible sources of testing error such as expiration date and storage conditions for the test strips. Always perform quality control testing per your facility's procedures and policies to make sure your system is working properly. The Owner's Booklet or QA Manual will assist you with this process.

The TRUEbalance system is optimized to give accurate results with fresh, capillary whole blood samples. Refer to the TRUEbalance Owners Booklet and TRUEbalance Strip Instructions for Use for further information.

Resources to learn about and obtain Proficiency Samples:

College of American Pathology (CAP) www.cap.org

American Association of Bioanalysts www.aab.org

TRUEbalance™ Quality Assurance / Quality Control Manual

Meter Specifications

Result Range: 20 - 600 mg/dL

Sample Size: Minimum 1.0 microliters (1.0 µL)

Sample Type: Fresh capillary whole blood from the finger or forearm,

Test Time: 10 seconds

Result Value: Plasma calibrated

Assay Method: Electrochemical

Reference Method: Yellow Springs Instrument (YSI)

Power Supply: One 3V lithium battery #CR2032 (non-rechargeable)
Total power when active at full battery = 8.6 mW

Battery Life: Approximately 1,100 tests or 1 years

Automatic Shut-off: After 2 minutes of non-use

Weight: 1.66 ounces

Size: 3.42" x 2.15" x 0.67"

Memory Size: 365 Blood Test results; 1 Control Test result

System Operating Range (Meter and Test Strips):

Relative Humidity: 10 - 90% (non-condensing)

Temperature: 50° - 104°F

Hematocrit: 30 - 55%

Note: *Use within specified environmental conditions only.*

Chemical Composition

TRUEbalance Test Strips: Glucose Oxidase (*Aspergillus sp.*),
mediators, buffers and stabilizers

TRUEcontrol Glucose Control Solution: Water, d-glucose, buffers,
viscosity enhancing agent, salts, dye and preservatives

TRUEbalance™ Quality Assurance / Quality Control Manual

Material Safety Data Sheet

Section 1 : Product Information

Product Name : TRUEbalance Blood Glucose Test Strips

Date Prepared : 24 June 2009

Section 2 : Composition / Information on Ingredients

Vial: Silica Gel, Polypropylene, Polyethylene

Test Strips: Glucose oxidase (*Aspergillus* sp.), mediators, buffers and stabilizers

Test Strip Box and Package Insert: Paper

Section 3 : Hazard Identification

No significant immediate hazards for emergency response are known.

Section 4 : Emergency First Aid Procedures

Eye: No first aid required.

Skin: No first aid required for contact with skin.

Ingestion: No first aid required from ingestion.

Inhalation: No first aid required.

Section 5 : Fire and Explosion Hazard Data

Flash Point (Method Used): Vial - > 450°F (estimated), Test Strips - N/A

Flammable Limits: N/A

General Hazard: Solid material may burn at or above the flashpoint. If thermally decomposed, flammable/toxic gases may be released. Toxic gases will form upon combustion. Hazardous combustion products may include and are not limited to: carbon monoxide, carbon dioxide.

Special Fire Fighting Procedures: Use water spray to cool fire exposed surfaces and to protect personnel. Isolate “fuel” supply to fire. Extinguish the fire by cooling with water spray. Respiratory and eye protection required for fire fighting personnel.

Unusual Fire and Explosion Hazards: None determined.

TRUEbalance™ Quality Assurance / Quality Control Manual

Section 6 : Spill or Leak Procedures

Steps to be taken in case material is released or spilled: Contain material to prevent contamination of soil, surface water and ground water. May be slipping hazard.

Section 7 : Handling and Storage

Store at temperatures and conditions as indicated on the product label. Store in original container and keep vial closed.

Section 8 : Personal Protection

Ventilation: Use general room ventilation.

Respiratory Equipment: None.

Protective Gloves: None

Eye Protection: None

Other Protective Equipment/Clothing: None

Section 9 : Physical Data

Appearance and odor: Vial - Vial with desiccant liner, Test Strips - Plastic strip with reaction area.

pH: N/A

Specific Gravity: N/A

Boiling Point: N/A

Melting Point: N/A

Vapor Pressure: N/A

Evaporation Rate: N/A

Solubility in Water: N/A

Section 10 : Reactivity Data

Stability: Stable.

Conditions to Avoid: Product can oxidize and decompose at elevated temperatures. Avoid putting water inside of vial, exothermic reaction will occur. Temperatures above 300°F may cause product degradation and self combustion.

Substances to Avoid: Avoid contact with strong acids and oxidizing materials.

Hazardous Decomposition Products: Flammable hydrocarbons.

Hazardous Polymerization: Will not occur.

TRUEbalance™ Quality Assurance / Quality Control Manual

Section 11 : Toxicological Information

Chronic Effects of Overexposure: None currently known.

Carcinogen or Suspected Carcinogen: None of the compounds present greater than 0.1% are listed as a carcinogen or suspected carcinogen.

Medical Conditions Aggravated by Exposure: None currently known.

Acute Toxicity Values: Not applicable.

Section 12 : Ecological Information

Ecological effects of this product have not been determined.

Section 13 : Disposal

Primary Container Type: Vial with 50 test strips.

Waste Disposal Method: Each disposal facility must determine proper disposal methods to comply with local, state, and federal environmental regulations.

TRUEbalance™ Quality Assurance / Quality Control Manual

Material Safety Data Sheet

Section 1 : Product Information

Product Name : TRUEcontrol Glucose Control Solution - Levels 0, 1 and 2

Date Prepared : 19 September 2008

Section 2 : Composition / Information on Ingredients

Bottle: Polypropylene, polyethylene

Control Solution: Water, d-glucose, viscosity enhancing agents, inorganic salts, amaranth and preservatives.

Control Solution Box and Package Insert: Paper

Section 3 : Hazard Identification

No significant immediate hazards for emergency response are known.

Section 4 : Emergency First Aid Procedures

Eye: Flush with copious amounts of water

Skin: Flush with water

Ingestion: Contact physician

Inhalation: Contact physician

Section 5 : Fire and Explosion Hazard Data

Flash Point (Method Used): Bottle - N/A, Control Solution - N/A

Flammable Limits: N/A

General Hazard: N/A

Special Fire Fighting Procedures: N/A

Unusual Fire and Explosion Hazards: None determined.

Section 6 : Spill or Leak Procedures

Steps to be taken in case material is released or spilled: Contain material to prevent contamination of soil, surface water and ground water. May be slipping hazard.

TRUEbalance™ Quality Assurance / Quality Control Manual

Section 7 : Handling and Storage

Store at temperatures and conditions as indicated on the product label. Keep bottle tightly closed when not in use.

Section 8 : Personal Protection

Ventilation: Use general room ventilation.

Respiratory Equipment: None.

Protective Gloves: None

Eye Protection: None

Other Protective Equipment/Clothing: None

Section 9 : Physical Data

Appearance and odor: Bottle - plastic bottle with cap, Control Solution - Red liquid

pH: N/A

Specific Gravity: N/A

Boiling Point: N/A

Melting Point: N/A

Vapor Pressure: N/A

Evaporation Rate: N/A

Solubility in Water: N/A

Section 10 : Reactivity Data

Stability: Stable.

Conditions to Avoid: N/A

Substances to Avoid: Avoid contact with strong acids and oxidizing materials.

Hazardous Decomposition Products: Flammable hydrocarbons.

Hazardous Polymerization: Will not occur.

Section 11 : Toxicological Information

Chronic Effects of Overexposure: None currently known.

Carcinogen or Suspected Carcinogen: None of the compounds present greater than 0.1% are listed as a carcinogen or suspected carcinogen.

Medical Conditions Aggravated by Exposure: None currently known.

Acute Toxicity Values: Not applicable.

TRUEbalance™ Quality Assurance / Quality Control Manual

Section 12 : Ecological Information

Ecological effects of this product have not been determined.

Section 13 : Disposal

Primary Container Type: Bottle with 3 mL Glucose Control Solution.

Waste Disposal Method: Each disposal facility must determine proper disposal methods to comply with local, state, and federal environmental regulations.



Section 2:

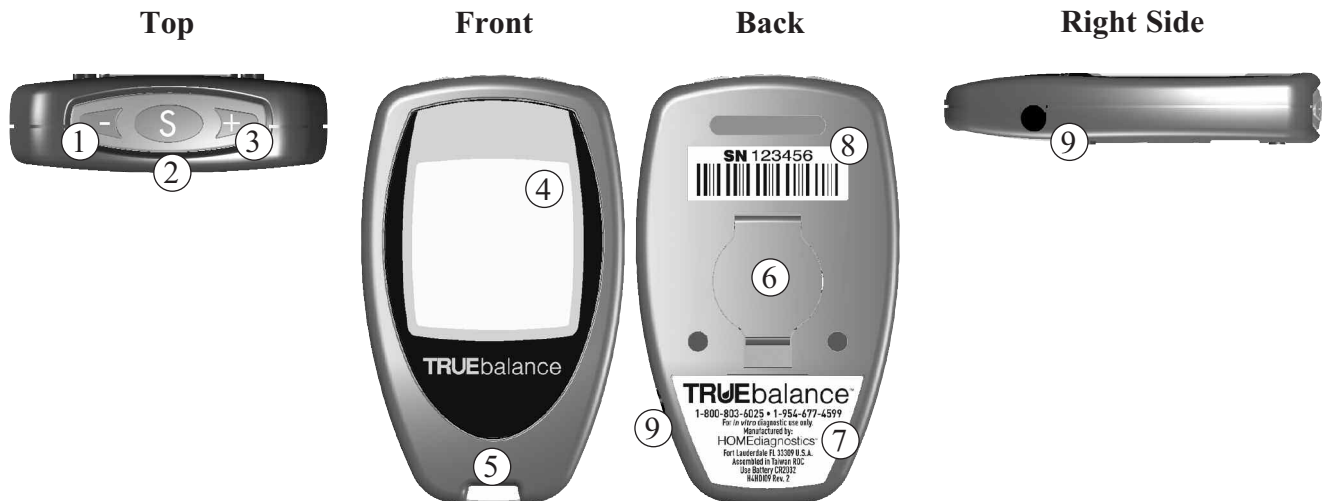
Description of System



TRUEbalance™ Quality Assurance / Quality Control Manual

Description of System

Meter



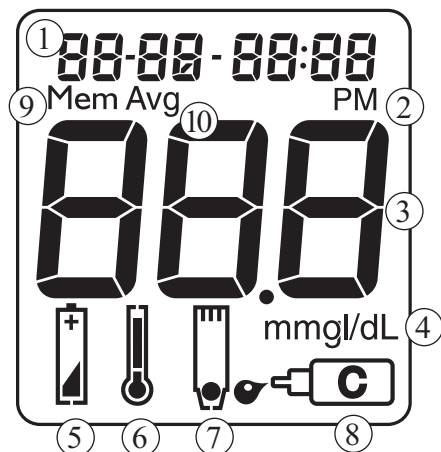
1. **“-“ Button** – Remove Control Bottle Symbol, decrease numbers in Set Up, move backwards by time / date when viewing results in Memory.
2. **“S” Button** – Turn Meter on/off for Memory/Set Up, view / scroll Morning Average and results in Memory.
3. **“+” Button** – Add Control Bottle Symbol, increase numbers in Set Up, move forward by time / date when viewing results in Memory.

***Note:** Use of Memory function is not recommended in a multi-patient setting.*

4. **Display Screen** – Shows results, messages, user prompts, information (see next page for full explanation).
5. **Test Port** – Place to insert TRUEbalance Test Strip
6. **Battery Door** – Open to replace battery. Use one non-rechargeable 3V lithium battery (#CR2032), positive (“+”) side up (*see Section 7: Care and Storage of System, Battery Replacement, for more details*).
7. **Meter Label** – Contains phone number to call for assistance.
8. **Serial Number** – Identifies Meter when calling for assistance.
9. **Data Port** – Call for assistance or for more information.

TRUEbalance™ Quality Assurance / Quality Control Manual

Full Display



Full Display Components:

1. **Time, Date, 14/30 Day Average**
2. **Time is PM** (*Note: AM does not appear.*)
(*Note: AM or PM not an option for factory set 24-hour clock.*)
3. **Test Result**
4. **Units of Measure** (*Note: Factory set, cannot be changed by user.*)
5. **Battery Symbol**
6. **Temperature Symbol**
7. **Drop Symbol**
8. **Control Symbol**
9. **Result is from Memory**
10. **Result is from 14/30 Day Average**

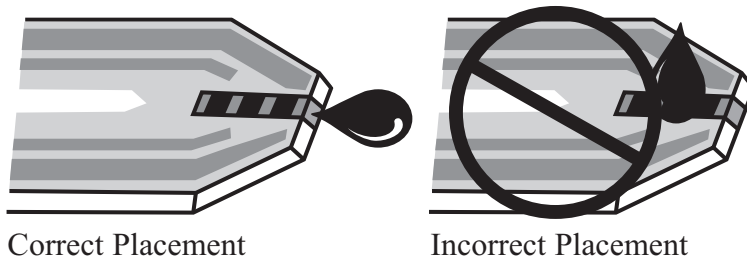
Test Strip



1. **Contact End** - Insert into Test Port with Contacts (metallic blocks) facing up.
2. **Sample Tip** - Bring sample (fresh, capillary or Glucose Control Solution) to edge of Tip. Capillary action draws sample into Test Strip for testing.

TRUEbalance™ Quality Assurance / Quality Control Manual

Sample Placement



- Allow sample (blood or Control) to be drawn into Sample Tip.
- Do not smear or scrape sample with Tip of Test Strip.
- Do not apply more sample to the Test Strip after removing the Test Strip from the sample drop.
- Do not apply blood or Control to top of Test Strip.
- Do not insert Sample Tip into the Meter.

Note: Use Test Strip quickly after removal from vial. Strips that have been left out of vial too long will give error message when used.

Note: Inserting the Test Strip backwards (Sample Tip into Test Port) after sampling may cause the Meter not to turn on. If Meter does not turn on, see Section 8: Troubleshooting.

TRUEbalance™ Quality Assurance / Quality Control Manual

Test Strip Vial Label

| | | |
|-------|---------------|---|
| LOT | EA645A4 | ① |
| ② EXP | 2012/10/31 | |
| 0 | 31-61 mg/dL | |
| 1 | 87-117 mg/dL | ③ |
| 2 | 247-335 mg/dL | |
| ② | May 30, 2012 | |

1. **Lot Number (LOT)** - Used for identification of lot for QC Form, used as a reference if calling for assistance.
2. **Expiration Dates (EXP)** - The printed Expiration Date is located on the Test Strip vial next to **EXP**. Write the date first opened on vial label. Discard vial and unused Test Strips if either date printed after **EXP** on Test Strip vial label or 120 days after date written on vial label has passed.


CAUTION! *Use of Test Strips or Glucose Control Solution past the Expiration Dates may give incorrect test results. Discard out-of-date products and test with new products.*

3. **Control Range** - Range of numbers in which Control Test result must fall to assure the System is working properly.

Glucose Control Solution Bottle Label

| | | |
|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| ③ | TRUEcontrol Glucose Control/Control de Glucose Levels/Niveles: 0, 1, 2 | LOT 8LOA18 EXP 2012/10/31 May 30, 2012 |
| | Manufactured for/Fabricado para: HOME Diagnostics Fort Lauderdale FL 33309 USA For in vitro diagnostic use only. Store in a dry place at room temperature between 36-86°F (2-30°C). DO NOT REFRIGERATE OR FREEZE. MSHD101 Rev. 4 | |
| | ① ② | |

1. **Lot Number (LOT)** - Used for identification of lot for QC Form, used as a reference if calling for assistance.
2. **Expiration Dates (EXP)** - The printed Expiration Date is located on the Control bottle label next to **EXP**. Write the date first opened on bottle label. Discard bottle and unused Control Solution if either date printed after **EXP** on Control bottle label or 3 months after date written on bottle label has passed.
3. **Control Level** - Three levels of TRUEcontrol Glucose Control Solution are available, Levels 0, 1, and 2. We recommend testing at least 2 levels of Control (*see Section 3: Quality Control*). For testing frequency and the number of Control levels tested, refer to your facility quality control procedure/policy.



Section 3:

Quality Control



TRUEbalance™ Quality Assurance / Quality Control Manual

Getting Started

The Meter turns on automatically when a Test Strip is inserted into the Test Port or when  Button is pressed.

The TRUEbalance is a no-coding system, which means the Meter does not have to be coded to each lot of test strips.

The Meter turns off automatically after the Test Strip is removed from the Test Port or after 2 minutes of non-use.

Meter comes with pre-set time and date. Before using the Meter for the first time or after a battery change, check the time and date and update as needed (*see Section 5: Set Up of Time and Date*).

TRUEbalance™ Quality Assurance / Quality Control Manual

Quality Control Testing

Quality Control procedures are used to detect errors that may occur due to test system errors, product defects, adverse environmental conditions and variance in operator performance. Ongoing QC procedures are also used to detect any performance issues of the System over time. Facility Quality Control Testing Policy and Procedure should adhere to the manufacturer's instructions for use and regulatory guidelines set forth by appropriate state, regional or national licensing or accrediting agencies.

TRUEbalance is a no-coding system, which means the Meter does not have to be coded to each lot of Test Strips.

To assure accurate and reliable results, TRUEbalance offers two kinds of Quality Control Tests. These tests ensure that TRUEbalance is working properly and testing technique is good.

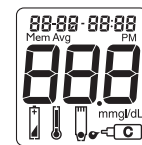
Automatic Self-Test

An automatic self-test is performed by the Meter each time a TRUEbalance Test Strip is inserted correctly into the Test Port.

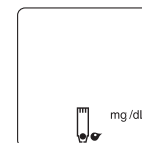
After inserting the Strip into the Test Port, if the full Display (showing no missing segments, see *Description of System, Section 2*) followed by the Drop Symbol appears, the Meter is working properly.

If an error message (E-1, E-2 etc.) appears in the Display after inserting a Test Strip, the Meter will not perform a glucose test. See *Display Messages, Section 8* for more information on error messages.

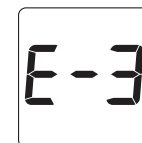
CAUTION! *If any segments are missing in the Display when the Test Strip is inserted into the Test Port, do not use the Meter for testing. Call for assistance using the phone number on the QA/QC Manual cover.*



Full Display



Display



TRUEbalance™ Quality Assurance / Quality Control Manual

Control Test

Use **ONLY** TRUEcontrol Glucose Control Solution to check the performance of the System. It is important to perform Control Tests with more than one level of Control to assure that the System is working properly and testing technique is good. Three levels of TRUEcontrol Glucose Control Solution (Levels 0-2) containing known amounts of glucose are available. Call the phone number on the QA/QC Manual cover or contact your supplier to order different levels of Control Solution. Control Test(s) should be performed:

- Before using the System for the first time,
- For practice to ensure that testing technique is good,
- When opening a new vial of Strips,
- If results seem unusually high or low based on the patient's condition,
- If Strip vial has been left open or exposed to extreme heat, cold or humidity,
- Whenever a check on the performance of the System is needed, or
- If Meter damage is suspected (Meter dropped, crushed, wet, etc.).

CAUTION! *Glucose Control ranges printed on the Test Strip vial are ranges for Control Tests results only. These ranges are not to be used by patients for blood glucose management. Contact a Doctor or Diabetes Healthcare Professional for individualized blood glucose target ranges. DO NOT consume Glucose Control.*

How to Perform a Control Test

Use the Quality Control Log located in *Section 10: Forms* to record Control Test results.

1. Allow Control bottle, vial of Test Strips and Meter to adjust to room temperature (59° - 86°F).
2. Check dates on Control bottle label and Test Strip vial label.
 - Do not use Control if 3 months past written opened date *or* after **EXP** date printed on Control bottle label.
 - Do not use Test Strips 120 days past written opened date *or* after **EXP** date printed on Test Strip vial label.Discard out of date products and use new products if either date has passed.
3. Swirl or invert Control bottle gently to mix Control. **DO NOT SHAKE!**

| | |
|--------------|---------------|
| LOT | EA645A4 |
| EXP | 2012/10/31 |
| 0 | 31-61 mg/dL |
| 1 | 87-117 mg/dL |
| 2 | 247-335 mg/dL |
| May 30, 2012 | |

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| TRUEcontrol Glucose Control/Control de Glucosa EXP/ANV Manufactured for/Fabricado para: HOME Diagnostics Fort Lauderdale, FL 33309 USA For in vitro diagnostic use only. Store in a dry place at room temperature between 36-86°F (2-30°C). DO NOT REFRIGERATE OR FREEZE. MSHD01 Rev. 4 | |
| LOT | 8LOA18 |
| EXP | 2012/10/31 |
| May 30, 2012 | |

TRUEbalance™ Quality Assurance / Quality Control Manual

4. Open Test Strip vial by pushing up under the lip of the vial cap. Remove one Test Strip. Close vial immediately by firmly pressing down on the top of the vial cap.

Note: Use Test Strip quickly after removal from vial. Test Strips that have been left outside the vial too long will give an error message. If an error message appears in the Display, discard the old Test Strip and test with a new Test Strip.

5. With Meter off, insert the Test Strip Contact End (Contacts facing up) into the Test Port. Meter turns on. Keep the Test Strip in the Meter until testing is complete.

6. Wait until the **Drop Symbol** appears in the Display.

Note: If Test Strip is removed before testing is finished, an error message appears. Remove and discard old Test Strip. Test with new Test Strip.

7. Remove cap from Control bottle. Turn Control bottle upside down. Squeeze one drop of Control onto a clean tissue. Wipe off bottle tip.

8. Gently squeeze another drop of Control onto a small piece of unused aluminum foil, clear plastic wrap, or a clean, non porous surface. (Discard foil/wrap or clean area after use.)

9. While Test Strip is still in the Meter, touch edge of Test Strip Sample Tip to drop of Control and allow drop to be drawn into Test Strip. Remove Test Strip from the drop when Meter beeps. Meter is testing.

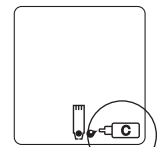
Note: If Meter does not start countdown soon after drawing up sample, discard Test Strip. Repeat the test with a new Test Strip. If problem persists, See Section 8: Troubleshooting.

10. Control Test result is displayed. Compare the Meter result to the Control Range printed on the Test Strip vial label for the Control level that is being tested. If the result is in range, the System can be used for testing blood. If the result is not within range, repeat the test using a new Test Strip.

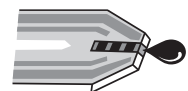
CAUTION! If Control Test is outside of the correct range, perform test again using a new Test Strip and a new drop of Control. If the result is still outside the correct range, the System should not be used for testing blood. Call for assistance.

11. Record the result in the TRUEbalance Quality Control Log (see Section 10: Forms).

12. Discard the Test Strip into an appropriate container. The Meter turns off.

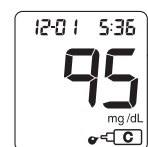


Control Symbol



Control Level

| | | |
|---|---------|-------|
| 0 | 31-61 | mg/dL |
| 1 | 87-117 | mg/dL |
| 2 | 247-335 | mg/dL |





Section 4:

Blood Glucose Testing



TRUEbalance™ Quality Assurance / Quality Control Manual

Blood Glucose Testing

Sample Information

Fresh, capillary whole blood from the finger or forearm is the recommended sample to be used for testing blood glucose. Always check with the Doctor or Diabetes Healthcare Professional before using a sample from the forearm. Results from the forearm are not always the same as results from the fingertip. Use fingertip instead of forearm:

- Within 2 hours of eating, exercise, or taking insulin,
- If the patient's blood glucose may be rising or falling rapidly or their results often fluctuate,
- If the patient is ill or under stress,
- If the glucose result may be low or high,
- If symptoms of low or high glucose levels may not be evident.¹

For evaluation where TRUEbalance blood glucose results are compared to blood glucose results given by a laboratory instrument, it is recommended that capillary whole blood obtained from the same sampling site be used for both the laboratory instrument as well as the TRUEbalance System. Laboratory tests should be performed within 30 minutes of a blood glucose meter test to minimize the changes in glucose values due to glycolysis. Results from the TRUEbalance System are considered accurate if within $\pm 20\%$ of laboratory results. If patient has recently eaten, finger results from the TRUEbalance System can be up to 70 mg/dL higher than venous laboratory results.²

The TRUEbalance is a no-coding system, which means the Meter does not have to be coded to each lot of test strips.

The TRUEbalance System cannot be used on neonates. Perform laboratory glucose tests on critically ill patients.

Do not use venous blood for testing with the TRUEbalance System.

TRUEbalance™ Quality Assurance / Quality Control Manual

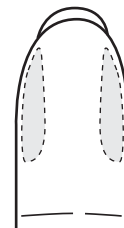
Obtaining a Blood Sample for Blood Glucose Testing

Refer to your facility approved method for lancing to obtain a blood sample for blood glucose testing. Follow OSHA precautions for blood-borne pathogens.

Note: Lancets are for single use only.

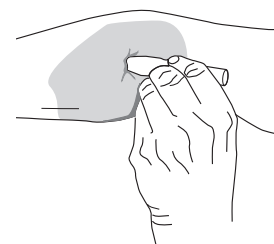
Tips for Fingertip Sampling

1. Select fingertip. Clean area with soap and warm water, rinse or use an approved disinfectant to clean the area. Dry thoroughly.
2. Lance finger.
3. To help blood drop form, lower the hand to a level below the heart and gently massage the finger from palm to fingertip. Allow the blood drop to form before attempting to apply the Test Strip.
4. Discard all biohazard materials into appropriate container.



Tips for Forearm Sampling

1. Select area. Clean the area with soap and warm water, rinse or use an approved disinfectant. Dry thoroughly.
2. Rub area vigorously or apply a warm, dry compress to increase blood flow.
3. Lance forearm.
4. Discard all biohazard materials into appropriate container.



TRUEbalance™ Quality Assurance / Quality Control Manual

How to Perform a Blood Glucose Test

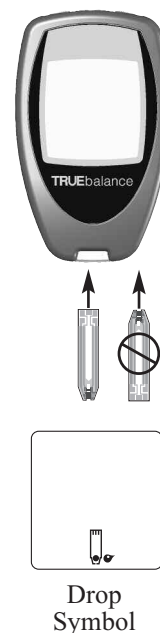
1. Check dates on Test Strip vial label.
 - Do not use Test Strips 120 days past written opened date *or* after **EXP** date printed on Test Strip vial label.
2. Clean the area to be lanced with an approved disinfectant. Dry thoroughly.
3. Remove one Test Strip from Test Strip vial by pressing up under the lip of the vial cap. Close Test Strip vial immediately by pressing firmly down on the top of the vial cap.

Note: Use Test Strips quickly after removal from Test Strip vial. Test Strips that have been left out of the vial too long will give an error message. If error message displays, discard the old Test Strip and test with a new Test Strip.

4. With Meter off, insert the Test Strip Contact End (Contacts facing up) into the Test Port. The Meter turns on. Keep the Test Strip in the Meter until the test is complete.

Note: Removing the Test Strip before the result is displayed cancels the test. An error message appears. Retest with a new Test Strip and do not remove the Test Strip from the Meter before the result is displayed.

5. Wait until the **Drop Symbol** appears in the Display.
6. Obtain the blood sample. Allow blood drop to form (*see Section 4: Blood Glucose Testing, Obtaining a Blood Sample*).



TRUEbalance™ Quality Assurance / Quality Control Manual

7. With Test Strip still in Meter, touch edge of Test Strip Sample Tip to sample and hold. Allow blood to be drawn into Test Strip. Remove Test Strip from sample when Meter beeps. Meter is testing.

Note: *If Meter does not start countdown in the Display soon after touching the sample to the Sample Tip, discard the Test Strip. Repeat the test with a new Test Strip and a new sample. If problem persists, see Section 8: Troubleshooting.*

8. After the test is finished, the blood glucose result is displayed.
9. Discard the Test Strip into the appropriate container. The Meter turns off.
10. Record the result as required by your facility.

System Out of Range Warning Messages

WARNING!

The TRUEbalance System accurately reads blood glucose levels from 20 - 600 mg/dL.

If test result is less than 20 mg/dL, “Lo” appears in the Meter Display.

If the test result is greater than 600 mg/dL, “HI” appears in the Meter Display.

ALWAYS repeat the test to confirm low (“Lo”) or high (“HI”) results. If results still display “Lo” or “HI”, contact the Doctor or Diabetes Healthcare Professional immediately.





Section 5:

Set Up of Time and Date



TRUEbalance™ Quality Assurance / Quality Control Manual

Set Up of Time and Date

Note: Setting up the time and date may not be suitable for a multi-patient use of the System. Check with the facility procedures and policies before performing Set Up.

Note: If the Meter turns off at any time during the Set Up, go back to Step #1 under Time/Date and begin again.

Time/Date

1. Press and hold the “S” Button until tone sounds (around 30 seconds). Release “S” Button. The Full Display appears and the Meter goes into Set Up.

2. The hour flashes. To change, press “+” or “-“ Buttons on the top of the Meter to select the hour. Like many alarm clocks, to set “PM”, scroll through the hours until “PM” appears in the Display next to the time. Press the “S” Button to set.

Note: “PM” will not display if the Meter is factory set to a 24-hour clock.

3. The minutes flash. To change, press “+” or “-“ Buttons on the top of the Meter to select the minutes. Press the “S” Button to set.

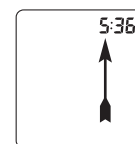
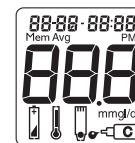
4. The month (number) flashes. To change, press “+” or “-“ Buttons to on the top of the Meter to select the month. Press the “S” Button to set.

5. The day (number) flashes. To change, press “+” or “-“ Buttons to on the top of the Meter to select the day. Press the “S” Button to set.

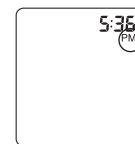
6. The year flashes. To change, press “+” or “-“ Buttons to on the top of the Meter to select the year. Press “S” Button to set.

Note: The Meter beeps every time a setting is confirmed (when the “S” Button is pressed).

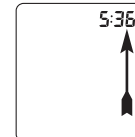
7. After all options have been set, review by pressing the “S” Button to scroll through Time and Date, making changes as necessary. After review, press and hold the “S” Button until the Display goes blank. Options are saved and the Meter turns off.



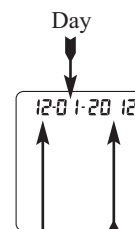
Hour



PM



Minutes



Month



Section 6:

Memory



TRUEbalance™ Quality Assurance / Quality Control Manual

Memory

Note: The use of the Memory features (Averages, Memory) may not be suitable for a multi-patient use of the System. Check with the facility procedures / policies before use.

Viewing Averages

The Averages feature displays the 14 and 30-day average blood glucose result using the earliest test result recorded between 4:00 am and 9:59 am (according to the meter clock) for every day testing was performed in the 14 and 30-day period. Control Test results are not included in the averages.

1. Start with the Meter off. Press and release the “S” Button. The Display scrolls through the 14 and 30 day Average values.
2. The Meter turns off after 2 minutes if no other buttons are pressed.

Note: If there are no Average values, three dashes are displayed for the 14 or 30 day Average results.

Viewing Memory

Note: The use of the Memory features (Averages, Memory) may not be suitable for a multi-patient use of the System. Check with the facility procedures / policies before use.

The TRUEbalance Meter’s Memory stores 365 blood glucose results and one Control Test result.

The oldest glucose result is removed from the Memory when the Memory is full and a new glucose result is added.

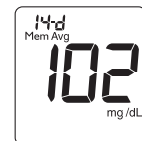
To access the Memory:

1. Press the “S” Button for a few seconds and release. The Meter turns on and the 14 and 30 day Average results are displayed. Press and release the “S” Button again to view the most recent Control Test result in Memory.

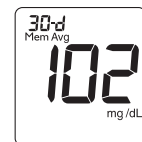
Note: Only one Control Test result is stored in the Memory.

2. Press the “+” Button and release to advance to the first blood glucose test result in Memory. Continue to press and release the “+” Button to advance through the blood glucose results. Holding the “+” Button scrolls through the results quickly. Press and release the “-” Button to go back through the results.

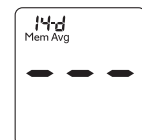
Control Test results display the Control Symbol. If no Control Test has been detected, the Display shows three dashes and the Control Symbol.



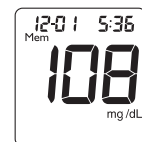
14 Day
Average



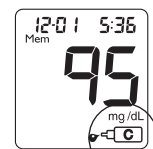
30 Day
Average



No Average



Memory



Control
Symbol

Control Test



Section 7:

Care and Storage of System



TRUEbalance™ Quality Assurance / Quality Control Manual

Caring for the TRUEbalance System

- Store the System (Meter, Test Strips, Glucose Control Solution) in an area protected from liquids, dust and dirt.
- Store the System in a dry place at room temperature, 36° - 86°F.
DO NOT REFRIGERATE OR FREEZE.

Meter

- Wipe Meter with a clean, lint-free cloth dampened with 10% bleach and water or an OSHA approved disinfectant.
- Never put Meter in liquids or allow any liquids to enter Test Port.
- Do not use 100% Isopropyl alcohol to clean the Meter. It may result in damage to the Meter Display.

TRUEbalance Test Strips

- Store Test Strips in original vial only. Do not transfer old Test Strips into new vial or store Test Strips outside of vial.
- Write the date first opened on Test Strip vial label. Discard vial and unused Test Strips if either **EXP** date printed on Test Strip vial label or 120 days after date written on vial label has passed.
- Close Test Strip vial immediately after removing one Test Strip. Store in a dry place at room temperature below 86°F.
DO NOT REFRIGERATE OR FREEZE.
- Do not reuse Test Strips.
- Do not bend, cut or alter Test Strips in any way.

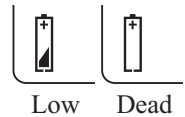
TRUEcontrol Glucose Control Solution

- Write the date first opened on Control bottle label. Discard bottle if either **EXP** date printed on bottle label or 3 months after date written on bottle label has passed.
- After use, wipe bottle tip clean and recap tightly.
- Store at room temperature, 36° - 86°F.
DO NOT REFRIGERATE OR FREEZE.

TRUEbalance™ Quality Assurance / Quality Control Manual

Battery Replacement

The Low Battery Symbol displays if the battery needs to be changed. The Meter will continue to function for about 50 more tests before Meter will not test. A dead battery displays the Battery Symbol, beeps, and then turns off. Use only a new 3V non-rechargeable lithium battery (#CR2032)




1. Lift Section on Battery Door.
2. Turn Meter over, tap gently on the palm of your other hand to loosen and remove battery.
3. Replace battery with a new non-rechargeable lithium battery (#CR2032), positive (“+”) side facing up. Close Battery Door.
4. Discard the old battery in an appropriate container.
5. Press the “S” Button to turn the Meter on. If Meter will not turn on, check that the battery was installed properly with “+” facing up. If not, remove and reinsert battery and try again. Call for assistance if problem persists.




Caution! *Batteries may explode if mishandled or incorrectly replaced. Do not dispose of battery in fire. Do not take apart or attempt to recharge battery. Dispose according to local/country regulations.*

Note: *If battery dies or is replaced, Time and Date may have to be reset. See Section 5: Set Up of Time and Date for more information.*



Section 8:

Troubleshooting



TRUEbalance™ Quality Assurance / Quality Control Manual

Troubleshooting

The following is a brief guide for Troubleshooting the most common errors when using TRUEbalance. If any problems arise that cannot be resolved by using this guide or the Display Messages, please call for assistance.

1) After inserting Test Strip into Test Port, Meter does not turn on.

Test Strip is inserted upside down or backwards.

- Remove Test Strip. Re-insert Test Strip correctly.

Strip not fully inserted.

- Remove Test Strip. Re-insert Test Strip fully into Meter.

Strip error.

- Remove Test Strip. Repeat with new Test Strip.

Dead or no battery.

- Replace battery.

Battery in backwards.

- Check placement of battery. Battery positive (“+”) side must face up.

Meter error.

- Call for assistance.

2) After applying the sample to the Test Strip, test does not start / Meter does not begin testing.

Sample too small.

- Repeat test with a new Test Strip and a larger sample drop.

Sample applied after two minute automatic shut- off of Meter.

- Repeat test with a new Test Strip and apply sample within 2 minutes.

Problem with Test Strip.


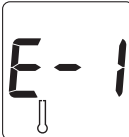






- Repeat test with a new Test Strip.

Problem with Meter.

- Call for assistance.



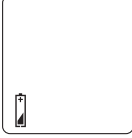
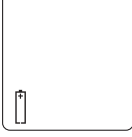

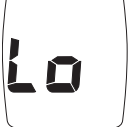
TRUEbalance™ Quality Assurance / Quality Control Manual

Display Messages

| Meter Display | What it Means | What to Do |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
|  | Temperature Error Temperature change too quick | Wait 10 minutes. Allow Meter and Test Strips to reach room temperature before testing. |
|  | Temperature Too Cold Meter temperature is less than 50°F (10°C) | Move Meter and Test Strips to an area between 50° - 104°F (10° - 40°C) before testing. |
|  | Temperature Too Hot Meter temperature is greater than 104°F (40°C) | Move Meter and Test Strips to an area between 50° - 104°F (10° - 40°C) before testing. |
|  | Sample Not Detected | Retest with a new Test Strip and a larger drop. Do not try to add an additional drop to the Test Strip. |
|  | Used Test Strip or Test Strip Outside of Vial too Long | Repeat test with a new Test Strip. If error persists, call for assistance |
|  | Meter Error | Call for assistance. |
|  | Test Strip Error | Retest with a new Test Strip. If error persists, call for assistance. |
|  | Strip Removed During Testing | Retest with a new Test Strip. If error persists, call for assistance. |

TRUEbalance™ Quality Assurance / Quality Control Manual

Display Messages

| Meter Display | What it Means | What to Do |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Meter Error | Call for assistance. |
|  | Communication Error | Turn Meter off and on again. If error persists, call for assistance. |
|  | Low Battery | About 50 tests remain before battery has to be replaced. |
|  | Dead Battery | Battery too low to run test. Replace battery. |
|  | • <u>WARNING!!</u> • High Results Result is greater than 600 mg/dL (33.3 mmol/L) | • <u>WARNING!!</u> • Retest with a new Test Strip. If the test result is still “HI” contact Doctor <i>immediately!!!</i> |
|  | • <u>WARNING!!</u> • Low Results Result is less than 20 mg/dL (1.1 mmol/L) | • <u>WARNING!!</u> • Retest with a new Test Strip. If the test result is still “LO” contact Doctor <i>immediately!!!</i> |



Section 9:

Training Certification Program



TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose System Training Certification Program

Trained and competent testing personnel are essential to good quality testing and patient care. Waived testing sites are subject to a high rate of personnel turnover. Personnel should be trained and competent in each test they will perform before reporting patient results. In addition, training should include aspects of safety (including Infection Control Policies) and Quality Control. The Risk Management, Chief Medical Officer, and other persons responsible for overseeing testing should ensure that testing personnel receive adequate training and are competent to perform the procedures for which they are responsible.⁶

Certificate Information

Home Diagnostics, Inc. (HDI) provides a training certificate for the use of the TRUEbalance Blood Glucose Monitoring System for point-of-care multi-patient facilities. The Training Certificate provides a record that the person listed on the Certificate has been trained correctly in the use of the TRUEbalance System and understands all procedures and limitations concerning the TRUEbalance System.

A. Certified Trainer

Certified Trainers are personnel from the facility who have received a Trainer's Certificate from Home Diagnostics, Inc. To obtain a Trainer's Certificate, the person must:

1. Read and be familiar with the entire Quality Assurance/Quality Control Manual and all product Instructions for Use (Test Strip, Glucose Control Solution, Owner's Booklet).
2. Complete the Training Checklist and Post Test included in this Manual.
3. Submit completed Post Test to:

HDI/LTC Training Certification
Attn.: Customer Care Manager
2400 NW 55th Ct.
Fort Lauderdale, FL 33309

Home Diagnostics, Inc. will return a Trainer's Certificate upon satisfactory completion of the Post Test (100% score required). Upon receiving the Trainer's Certificate from HDI, Certified Trainers are qualified to train appropriate personnel at their facility to be Approved Testers. Training Checklists and Certificates should be filed in the employee's file at the facility.

- **CERTIFIED TRAINERS SHOULD BE RE-CERTIFIED EVERY 12 MONTHS.**

TRUEbalance™ Quality Assurance / Quality Control Manual

B. Approved Testers

Approved Testers must be trained by Certified Trainers before they perform Control Tests or blood glucose testing using the TRUEbalance System. To become an Approved Tester:

1. Successfully complete the Training Checklist under the instruction of a Certified Trainer.
2. Demonstrate the proper technique for testing with the TRUEbalance System using the appropriate blood and Control samples.
3. Identify the facility's Quality Control Policy and Procedures, including documentation of Quality Control.

Upon the person's satisfactory completion of the above, the Certified Trainer documents the training, signs the Training Checklist and files the completed Checklist in the employee's file at the facility.

APPROVED TESTERS SHOULD BE RE-TRAINED EVERY 12 MONTHS BY A CERTIFIED TRAINER.

TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose System Training Checklist (Please print)

Name _____ Date ____/____/____

Title _____ Facility _____

Confirmed by _____ Date ____/____/____
Certified Trainer

1. The Tester has completed the following:

- _____ Read the Owner's Booklet
- _____ Read the Test Strip Instructions for Use (Insert)
- _____ Read the Glucose Control Instructions for Use (Insert)
- _____ Read the QA/QC Manual

2. Familiarization with the components of the System.

a. Meter

- _____ Location of serial number for the Meter
- _____ Location of phone number for assistance
- _____ Review of Meter buttons and functions

b. Test Strips

- _____ Identifies lot number
- _____ Writes open date on Test Strip vial label
- _____ Understands the Expiration Dates, both printed and written
- _____ Reviews proper handling of Test Strips including recapping of the Strip vial immediately after removing a Test Strip
- _____ Demonstrates proper insertion of the Test Strip into the Meter

c. Glucose Control Solution

- _____ Identifies lot number
- _____ Writes open date on Control bottle label
- _____ Understands the Expiration Dates, both printed and written
- _____ Identifies Control levels
- _____ Identifies Control ranges

TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose System Training Checklist

3. Quality Control Tests

- _____ Understands the manufacturer's instructions for control testing
- _____ Understands the purpose of the automatic self-test of the Meter upon insertion of a Test Strip into the Test Port
- _____ Understands the purpose of Control Tests, the frequency of testing, and the number of Control levels to be tested
- _____ Understands the testing temperature range and what may result if the testing temperature is out of range
- _____ Identifies the correct (unopened vs. opened) Expiration Dates on the Control bottle.
- _____ Identifies the correct Control range for the Control level and understands troubleshooting if the Control Test result is not within the acceptable range
- _____ Demonstrates the Control Test procedure using the Glucose Control Solution
- _____ Records the Control Test result on the TRUEbalance Quality Control Log

4. Blood Collection

- _____ Understands the proper technique of capillary blood collection for both finger and forearm samples
- _____ Understands when finger should be used instead of forearm
- _____ Demonstrates the ability to obtain a sufficient amount of blood for testing from both a finger tip and forearm
- _____ Understands limitations of forearm samples for testing

5. Blood Glucose Testing

- _____ Demonstrates proper blood glucose testing procedure for the TRUEbalance System
- _____ Understands limitations of forearm samples for testing
- _____ Understands the proper blood application to the Sample Tip and the significance of the Display Symbols

6. Blood Glucose Test Results

- _____ Demonstrates the proper documentation of test results
- _____ Understands troubleshooting if test results are not within the patient's target range (e.g. perform Quality Control Tests, repeat test, possible therapy change after consultation with Doctor or Diabetes Healthcare Professional, etc.)
- _____ Understands that the use of the Memory feature may not be appropriate for multi-patient facilities
- _____ Demonstrates proper disposal of biohazardous materials per facility policies and procedures

7. Care and Storage

- _____ Understands proper infection control policy and procedure for cleaning and disinfecting meter
- _____ Demonstrates battery replacement
- _____ Understands proper storage of Meter, Test Strips, and Glucose Control Solution

TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose System Certified Trainer Post Test (Please print)

Name _____ Date ____/____/____
Title _____ Phone/Fax _____
Facility _____ E-Mail _____
Address _____

True or False:

1. All Healthcare Professionals performing blood glucose monitoring using the TRUEbalance System should complete the training program.
_____ True _____ False
2. The TRUEbalance System can be used on neonates.
_____ True _____ False
3. Quality Control Testing should be performed per your facility's policies and procedures.
_____ True _____ False
4. Any control solution can be used with the TRUEbalance System.
_____ True _____ False
5. Critically ill patients (shock, hyperglycemic-hyperosmolar state, with or without ketosis) should be tested with the TRUEbalance System.
_____ True _____ False
6. If the Meter becomes soiled, wipe it off with a lint free cloth dampened with an OSHA approved disinfectant.
_____ True _____ False
7. The battery should be replaced with an AAA alkaline battery.
_____ True _____ False

TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose System Certified Trainer Post Test

Multiple Choice: (choose only one answer for each question)

1. Training on the use of the TRUEbalance System consists of reviewing the following:
 - a) The QA/QC Manual
 - b) The Owner's Booklet
 - c) Test Strip Instructions for Use
 - d) Control Solution Instructions for Use
 - e) All of the above
2. The Glucose Control open-bottle expiration dating is
 - a) One week after opening.
 - b) 60 days after opening.
 - c) 3 months after opening.
 - d) The date printed on the bottle.
3. The Test Strips open vial expiration dating is
 - a) One month after opening.
 - b) 60 days after opening.
 - c) 120 days after opening.
 - d) The date printed on the vial.
4. If the Control Test result is out of range, it may be because
 - a) The Control Solution has expired.
 - b) The Test Strips have expired.
 - c) The cap was left off of the Control bottle.
 - d) All of the above.
5. The following sample type is appropriate for testing with the TRUEbalance System
 - a) Capillary Whole Blood.
 - b) Serum.
 - c) Plasma.
 - d) Clotted Blood.
 - e) Venous.
6. The following tests are used for Quality Control of the TRUEbalance:
 - a) One level of Glucose Control and a patient sample
 - b) One level of Glucose Control
 - c) A low level of Glucose Control and a high level of Glucose Control
 - d) Meter automatic self-test and a minimum of 2 levels of Glucose Control

TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Blood Glucose System Certified Trainer Post Test

Multiple Choice: (choose only one answer for each question)

7. Retraining of all personnel must be performed within
 - a) 6 months
 - b) 12 months
 - c) 8 months
 - d) 30 days

8. The Meter displays blood results as a:
 - a) Whole blood value.
 - b) Venous blood value.
 - c) Plasma value.
 - d) Serum value.

9. The phone number for assistance is located:
 - a) On the Owner's Booklet cover
 - b) On the cover of the QA/QC Manual
 - c) On the back Meter label
 - d) On the Test Strip Instructions for Use
 - e) All of the above

10. Forearm testing may not be appropriate in the following situations:
 - a) Within 2 hours of exercise
 - b) If the patient's glucose result often fluctuates
 - c) If the patient is under stress
 - d) All of the above



Section 10:

Forms



Meter Serial Number (7-digit number on Meter label below the bar code) ***Note any problems in Troubleshooting section below.**

[illegible]

| Date | Problem | Action | Initials |
|------|---------|--------|----------|
| | | | |
| | | | |
| | | | |

QUALITY CONTROL RECORD

Meter Serial Number _____ (7-digit number on Meter label below the bar code) ***Note any problems in Troubleshooting section below.**

[illegible]

*TROUBLESHOOTING

| Date | Problem | Action | Initials |
|------|---------|--------|----------|
| | | | |
| | | | |
| | | | |



Section 11:

TRUEbalanceTM Lifetime Warranty



TRUEbalance™ Quality Assurance / Quality Control Manual

TRUEbalance Limited Lifetime Warranty

Home Diagnostics, Inc. provides the following Warranty to the original purchaser of the TRUEbalance Blood Glucose Meter:

- 1) Home Diagnostics, Inc warrants this Meter to be free of defects in materials and workmanship at the time of purchase. If the Meter is ever inoperative, Home Diagnostics, Inc. will replace the Meter with an equivalent Meter, at its option, at no cost to the purchaser. Failure of the Meter due to abuse or use not in accordance with the instructions for use is not covered by this Warranty.
- 2) This Warranty does not include the battery supplied with the Meter.
- 3) Do not take the Meter apart. This action will void the Warranty and cause the Meter to display false results.
- 4) The duration of any implied Warranty, including any implied Warranty of merchantability or fitness for a particular purpose shall be limited to the lifetime in use with the original user in accordance with any state law to the contrary.
- 5) Home Diagnostics, Inc. disclaims liability for incidental or consequential damages for breach of any expressed or implied Warranty, including any implied Warranty of merchantability or fitness for a particular use with respect to the Meter. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusion may not apply.
- 6) This Warranty gives the user specific legal rights, and the user may also have other rights which vary state to state.

Your Home Diagnostics, Inc. Customer Care Representative will be able to provide detailed information regarding procedures for returning your Meter, if necessary.



Section 12:

References



TRUEbalance™ Quality Assurance / Quality Control Manual

References

1. U.S. Food and Drug Administration 2003. *Blood Glucose Meters, Getting the Most Out of Your Meter*. [Electronic Version]. Retrieved June 16, 2009: www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm.
2. Larsson-Cohn U: Difference between capillary and venous blood glucose during oral glucose tolerance tests. *Scand J Clin Lab Invest* 36:805-808, 1976.
3. Food & Drug Administration. Draft Guidance for Industry and Staff. Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring System. [Electronic Version]. Retrieved February 5, 2007: <http://www.fda.gov/cdrh/oivd/guidance/1603.pdf>.
4. Data on file.
5. American Diabetes Association. Standards of Medical Care, Diabetes Care 33 (Suppl. 1): S11-S61, 2010. [Electronic Version]. Retrieved January 11, 2010. http://care.diabetesjournals.org/content/33/Supplement_1/S11.full.
6. Good Laboratory Practices for Waived Testing Sites. [Electronic Version]. Retrieved July 14, 2008: www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm.